

AMENDMENTS TO THE SPECIFICATION

Please add the following paragraph prior to the paragraph beginning on page 1, line 2 of the specification:

(New) The present application is a Divisional of U.S. Application Serial No. 09/832,356 filed April 09, 2001, pending, which is a continuation of U.S. Application Serial No. 9/102,827 filed June 23, 1998, which is now U.S. Patent No. 6,213,941, which is a Divisional of U.S. Application Serial Number 08/603,758 filed on February 20, 1996 which is now U.S. Patent No. 5,894,843. U.S. Application Serial Numbers 09/832,356; 09/102,827 and 08/603,758 and U.S. Patent Nos. 6,213,941 and 5,894,843 are hereby incorporated herein, in their entireties, by reference thereto.

Please amend the paragraph beginning on line 1 of page 3 as follows:

(Amended) instruments. If ~~special~~ specially designed instruments were available so that the CABG procedure could be performed on the beating heart, the beating-heart CABG procedure would be more widely practiced and the treatment of cardiovascular disease in a significant patient population would be improved.

Please amend the paragraph beginning on line 3 of page 4 as follows:

(Amended) A current practice is for the surgeon to place sutures through the heart tissue and, by exerting opposing tension on the sutures, stretch the tissue surrounding the anastomosis to partially reduce the motion of the heart while the graft is installed. This approach is far from ideal. Alternatively, a suction device may be attached to the surface of the heart to fix the motion of the outer layer of surface tissue. In such cases, a suction ~~device typically has~~ device, typically having several ports incorporated into an instrument, may be attached to the heart to apply a negative pressure to the

surface tissue. The negative pressure essentially attaches the surface tissue to the apparatus thereby fixing the position of a portion of the surface of the heart. Such devices are described in U.S. Patent No. 5,727,569 ~~co-pending application no. _____~~.

Please amend the paragraph beginning on line 5 of page 5 as follows:

(Amended) The advantages provided to a surgeon by the instruments and techniques of the invention allow the beating heart CABG procedures to be performed more rapidly, with less trauma to the patient, and without CPB or cardioplegia. This invention provides ~~an alternative approach to the suction apparatus by providing~~ devices and methods for stabilizing the motion of the heart and exposing an artery or other surgical target using mechanical instruments specially designed to apply a stabilizing force to the heart to minimize the motion of the beating heart during a surgical procedure. The invention enables a surgeon to readily and rapidly perform a beating-heart CABG procedure without the need for cardioplegia or cardiopulmonary bypass. In particular, the methods and devices described here enable the surgeon to stabilize the heart such that an anastomosis can be more readily accomplished by enabling the surgeon to attach the graft to a target coronary artery whose motion is minimized for the duration of the surgical procedure.

Please amend the paragraph beginning on line 16 of page 5 as follows:

(Amended) Pursuant to the invention, a stabilizing device is introduced through a suitable opening in the chest to provide access to the beating heart. By contacting the heart with the stabilizing means of this invention and by exerting a stabilizing force on the heart, the motion of the heart caused by the contraction of the heart muscles is effectively eliminated such that movement of the target artery at the site of the surgery is minimized. By contacting the heart with exposure members of the stabilizing means, the exposure members can be moved to further expose the target artery. The remainder of the heart may be

Please amend the paragraph beginning on line 1 of page 6 as follows:

(Amended) allowed to contract normally or may have additional devices in place to support the heart or to restrain its motion. An important advantage of this invention is derived from the discovery

that an effective procedure can be followed using the devices of the inventors invention to provide an advantageous technique for stabilizing the beating heart. The procedure requires exerting a stabilizing force on the beating heart using devices constructed as described herein. Typically, in separate steps, the surgeon contacts the heart with the stabilizing means, assesses the degree of movement at the site of the surgery and positions the stabilizing means proximate to the target coronary artery. With the stabilizing means in place, the surgeon applies a stabilizing force to the stabilizing means by applying a force such that the portion of the instrument in contact with the surface of the heart displaces the surface of the heart a sufficient distance that the contraction of the heart does not cause either vertical or horizontal motion at the surgery site. A portion of the stabilizing means is movable to further retract or displace the heart tissue to further expose or present the target artery. The stabilizing force is applied by the stabilizing means of the invention and comprised of exerting a mechanical force onto the beating heart at the location of the target coronary artery. Thus, an important aspect of this invention is the discovery that the beating heart may be effectively stabilized for the purpose of a surgical procedure by using a specially designed instrument as described herein to exert a mechanical stabilizing force on the exterior of the heart proximate to the site of the surgery.

Please amend the paragraph beginning on line 1 of page 7 as follows:

(Amended) may be attached to a retractor used to separate the ribs or to another fixed support. Alternatively, the stabilizing means may be attached to a semi-rigid ~~and formable~~ conformable arm which is rendered rigid ~~by~~ mechanically, chemically, or by human intervention. In certain preferred embodiments, the stabilizing means has an adjustable shaft means which may be oriented in several directions and has a fixture adapted to be attached to a retractor. In a preferred technique of the invention, the surgeon first performs a thoracotomy, thoracotomy and retracts the ribs using a retractor which is locked in an open position providing access to the beating heart. The surgeon then contacts the surface of the heart with the stabilizing means at a point proximate to the target coronary artery, and exerts a stabilizing force on the stabilizing means until the site of the surgery is substantially motionless. At this point, the adjustable shaft means is positioned and fixed in place by attachment to the retractor thereby rendering the target coronary artery substantially motionless for the duration of the procedure.

Please amend the paragraph beginning on line 1 of page 8 as follows:

(Amended) Figure 2 is Figures 2A and 2B show an alternate embodiment of a stabilizing means having a single shaft means associated with each contact member and where the shaft means are interconnected and can be moved independently about a pivot such that the contact members spread the surface tissue of the heart proximate to the target coronary artery to increase exposure of the target artery at the site of the anastomosis.

Please amend the paragraph beginning on line 6 of page 8 as follows:

(Amended) Figure 3 is a means for stabilizing the beating heart having a pair of contact members which ~~are~~ additionally comprise ~~comprised of~~ a spring-tensioned frame having an extension that engages and spreads the tissue at the site of the surgery to better expose the coronary artery.

Please amend the paragraph beginning on line 9 of page 8 as follows:

(Amended) Figure 4 is an inflatable means for stabilizing the beating heart having a sheath member with several pliable support attachments associated therewith which may include ~~or be~~ ~~comprised of~~ inflatable members which are positioned at one or several locations surrounding the heart and may have a lumen disposed within the sheath member for the introduction of air or a biocompatible fluid.

Please amend the paragraph beginning on line 14 of page 8 as follows:

(Amended) Figure 5 is a means for stabilizing the beating heart comprising a system which incorporates the retractor which spreads the ribs to provide surgical access to the heart. The stabilizing means ~~is comprised of~~ comprises a pair of stabilizing plates which may be used together with a lever device to improve exposure of the target coronary artery. Figure 5A is a partial side view of the system of Figure 5.

Please amend the paragraph beginning on line 8 of page 10 as follows:

(Amended) ~~This invention is~~ The present invention includes surgical instruments for stabilizing the beating heart and methods for their use. The means for stabilizing the beating heart ~~are comprised~~

ef comprises any of several alternative structures which engage the surface of the heart to stabilize the beating heart during coronary surgery. The instruments provide the capability to exert and maintain a stabilizing force on the heart by contacting the heart with the stabilizing means and by fixing the position of the stabilizing means throughout the duration of a surgical procedure.

Please amend the paragraph beginning on line 17 of page 12 as follows:

(Amended) Although the particular source and target artery of the anastomosis are determined clinically, a common minimally invasive bypass procedure on the beating heart comprises an anastomosis which forms a connection between the left internal mammary artery (LIMA) as the source artery and the left anterior descending artery (LAD) as the target artery. The LIMA to

Please amend the paragraph beginning on line 4 of page 14 as follows:

(Amended) Referring to Figure 1, a stabilizing means is comprised of comprises one or more, and preferably two, contact members 1, which are attached to a rigid, or semi-rigid connecting shaft 2 which is in turn connected to shaft means 3. The contact members 1 may be substantially planar or may be slightly curved to conform to the shape of the heart. The contact members 1 may have any of several alternate shapes including cylindrical members formed into a U-shape or may comprise a pair of substantially parallel members spaced apart in a parallel configuration such that a target artery can be positioned between the contact members. The shaped of the contact members may be varied depending on the clinical assessment by the surgeon, the design of the other features of the stabilizing means, or the design of other instruments used to complete the anastomosis. In some embodiments, as described herein, the contact members 1 may have apertures, openings or attachments to facilitate connection with sutures or other devices to achieve the requisite stabilization. In a preferred embodiment, a pair of substantially planar rectangular contact members 1 are attached at one end to a continuous connecting shaft 2 and are oriented in a substantially parallel fashion such that a target cardiac artery is positioned therebetween and passes along the length of the contact members 1 when the stabilizing means engages the heart. See figures Figures 9A-C. While the contact members 12 may each be connected to the connecting shaft 2 at one end, with the connecting shaft 2 operably attached to shaft means

Please amend the paragraph beginning on line 11 of page 15 as follows:

(Amended) The shaft means 3 may be a simple rigid post or may be comprised of comprise a multi-component system designed to be adjustable in length and orientation at at least one point along its length. Thus, the length of the shaft means 3 and the orientation of the contact members 1 at the distal (lower) end of the shaft means 3 can be altered by the surgeon. Preferably, the length and orientation at the shaft means 3 relative to the contact members 1 can be adjusted by controls located at the proximate (upper) end of shaft means 3. This design provides the advantage that the surgeon can introduce the stabilizing means to the beating heart by placing the contact members 1 on the surface of the heart, exerting a stabilizing force, and then locking the contact members 1 in place relative to the shaft means 3. Furthermore, the surgeon may then lock the shaft means 3 into a fixed position by attachment to a stable support such as the retractor,

Please amend the paragraph beginning on line 1 of page 16 as follows:

(Amended) thereby maintaining the stabilizing force for the duration of the procedure. In one embodiment, the shaft means 3 has a housing 11 whose overall length is adjustable by a telescoping release 4 of additional housing 11 length operated by an annular thumbscrew 10 which tightens about the housing 11. The position and orientation of the contact members 1 relative to the shaft means 3 is adjustable by virtue of a locking ball joint 5 which is interposed between the connecting shaft 2 and which is located at the distal end of shaft means 3. The locking ball joint 5 allows the position of the shaft means 3 to be positioned with three degrees of freedom relative to the contact members 1.

Please amend the paragraph beginning on line 8 of page 16 as follows:

(Amended) Referring again to Figure 1, a locking ball joint 5 is provided by including a block 6 within the shaft means 3 which conformingly contacts the ball joint 5 and fixes the position of the ball joint 5. Block 6 is compressed against ball joint 5 when a threaded push block 7 is connected to a long allen 9 is actuated by means such as a thumbscrew 8 at the upper end of the shaft means 3. In operation, a rotation of the top thumbscrew 8 loosens the lower ball joint 5 to allow continuous positioning of the shaft means 3 relative to the contact members 1, and a counterrotation locks the ball joint 5 into place, fixing the position of the contact members 1 relative to shaft means 3.

Please amend the paragraph beginning on line 4 of page 17 as follows:

(Amended) Referring to Figure 1B, the contact members 1 preferably have friction means 4 associated with their bottom ~~surface 5~~ surfaces such that the contact members 1 more securely engage the beating heart when a stabilizing force is exerted on the shaft means 3. Friction The friction means 4 preferably comprises a textured surface covering the bottom surface 5 of the contact member 1, and may be comprised of several bio-compatible substances such as a textured rubber, textured or ridged aluminum, stainless steel or the like.

Please amend the paragraph beginning on line 18 of page 17 as follows:

(Amended) The shaft means 3 may also be ~~attached, to or comprised of, attached to, or comprise~~ a conformable arm which is used to position the stabilizing means against the heart and then to lock the stabilizing means in place once a stabilizing force has been exerted. The conformable arm is flexible and lockable

Please amend the paragraph beginning on line 1 of page 18 as follows:

(Amended) and may have several configurations including a plurality of links, segments or universal joints in serial configuration and having a cable fixture passed through the interior of the links which cause the entire conformable arm to become rigid by tightening the cable fixture. Also, the conformable arm may ~~be comprised of~~ comprise a synthetic gel or polymer contained within a conformable cylindrical housing which becomes rigid upon exposure to light or heat, such as the commercially available Dymax 183-M. Where the shaft means 3 is ~~further comprised of~~ further comprises the conformable arm, the conformable arm may be attached directly to the connecting shaft 2 or the contact members 1.

Please amend the paragraph beginning on line 9 of page 18 as follows:

(Amended) Referring to Figure 2, the stabilizer means may also ~~be comprised of~~ comprise a single shaft means 3 connected to each contact member 1. In a preferred embodiment, the shaft means 3 are interconnected at an intermediate pivot point 16 which permits the contact members 1 to be

continuously positioned in parallel fashion relative to one another. The proximate (upper) portion of the individual shaft means 3 may have grips adapted to be grasped by the hand or may have an anchor portion 15 for attachment to a retractor or other fixed support. As with the other embodiments described herein, the length of the shaft means 3 may be adjustable by a conventional telescope configuration. In such a configuration, a first shaft 18 has a partially hollow segment 17 adapted to receive the complimentary portion of the second shaft 19. Either first 18 or second 19 shafts may be connected to the contact members 1 and may each have a conventional locking mechanism (not shown). The shaft means may also have a tensioning spring mechanism having an axis 21 which is displaced between a portion of the shaft means 3

Please amend the paragraph beginning on line 1 of page 19 as follows:

(Amended) affixed to the contact members 1 and the remainder of the shaft means 3. In this configuration, the contact members 1 remain tensioned against the heart proximate to the anastomosis site when the proximal end of the shaft means 3 is affixed to a stable support. The shaft means may also comprise an interlocking mechanism 90 to fix the position of a single shaft 18 relative to the 18 to fix the position of a single shaft 18 relative to the other. This embodiment also preferably has a friction means 4 as described above attached to each contact member 1. An additional advantage of this embodiment is derived from the capability to move the contact members 1 apart from one another in a parallel configuration. Thus, the contact members 1 can first be positioned to engage the surface of the heart tissue, followed by the application of a stabilizing force in combination with spreading of the proximate(upper) end of the shaft means 3. Application of a stabilizing force causes the tissue on either side of the target artery to be stabilized. By coincidentally spreading the proximate portion of the shaft means 3, the tissue engaged by the contact members 1 is stretched to provide stabilization and improved exposure of the target coronary artery.

Please amend the paragraph beginning on line 14 of page 19 as follows:

(Amended) Referring to Figure 3, the contact members 1 may be further ~~comprised of~~ comprise a spring-tensioned frame ~~24~~ 210 having a movable frame extension 22 which may have pins or an associated friction means 4 to engage the tissue proximate to the target artery. The movement of the frame extension 22 is tensioned by a spring means 23 which draws the frame extension 22 toward the

contact member 1 after the frame extension 22 has been manually positioned to engage the tissue. The use of this embodiment of the invention is the same as is described for the other embodiments herein, with the frame extension 22 providing improved exposure of the target

Please amend the paragraph beginning on line 5 of page 20 as follows:

(Amended) Referring to Figure 4 shows an, this embodiment of the a stabilizing means is comprised of comprising an elongated sheath member 26 which wraps around the heart in a strap-like fashion to restrict the motion of the heart. This embodiment is particularly useful when access to the beating heart is provided by a sternotomy. The sheath member 26 is positioned to surround the heart and can be manipulated so that each end of the sheath member 26 extends out of the chest cavity through the sternotomy. If desired, at least one end of each sheath member 26 is attached to the retractor to secure the position of the sheath member 26. The sheath member 26 may have a plurality of support attachments 27 which engage the exterior of the heart to hold it in place. At the point where the support attachments 27 contact the surface of the heart, the support attachments 27 may have friction means 4 attached to the surface which is surfaces which are in direct contact with the heart. The support attachments 27 may have, or comprise or be comprised of inflatable members 28 which suction the heart against the sheath member 26, and absorb the motion of the heart while it is stabilized. Where the sheath member 26 has a plurality of inflatable members 28, the sheath member 26 is preferably further comprised of comprises at least one lumen 29 for introduction of air or a other biocompatible fluid to the inflatable members 28, which may be inflated separately or simultaneously. In the former instance, a separate lumen 29 is provided for each inflatable

Please amend the paragraph beginning on line 9 of page 22 as follows:

(Amended) Opposite the edge 32 27, at a point separate from the lever member 33, the stabilizing 30, 31 plate is connected to a shaft means 3 which holds the stabilizing plate 30, 31 in position and which may be manipulated relative to the lever member 33 to cause the edge 27 to engage the heart. The shaft means 3 is preferably affixed to each stabilizing plate 30, 31 at a point opposite the edge 27 and removed from the point where the lever member 33 contacts the stabilizer plate 30,31 at a location to maximize leverage when the stabilizer plates 30, 31 are drawn upwards at the point of attachment of the shaft means 3. The shaft means 3 may be constructed as described elsewhere herein

and should be of sufficient length to facilitate manipulation of the shaft means 3 by the surgeon. As noted, the shaft means may also be attached to the retractor to fix movement of the stabilizing plates 30, 31 during the procedure.

Please amend the paragraph beginning on line 10 of page 23 as follows:

(Amended) The embodiment shown in Referring to Figure 6, this embodiment of the invention is a means for stabilizing the beating heart wherein the shaft means ~~is comprised of~~ comprises a flexible, lockable arm 37 having a plurality of interconnecting links 38 which allow positioning of the flexible arm 37 in every direction until the desired configuration is achieved at which point the flexible arm 37 may be locked into a fixed configuration by tightening a cable fixture (not shown) attached to a cable 39 running axially through the interconnecting links 38. Each interconnecting link ~~is comprised of~~ comprises a ball portion 38a and a receiving portion 38b such that the ball portion 38a ~~38~~ fits conformingly within the receiving portion 38b. The proximate (uppermost) end of the flexible, lockable arm 37 can be attached to a stable support, or to the retractor. In a preferred embodiment, the flexible, lockable arm 37 is a series of interconnecting links 38 having a cable 39 running through the center of each interconnecting link 38 such that when tension is exerted on the cable

Please amend the paragraph beginning on line 1 of page 24 was amended as follows:

(Amended) 39, the flexible, lockable arm 37 is fixed in a rigid position. Figure 6 also shows an embodiment of the invention wherein the contact members 1 ~~are comprised of~~ comprise a pair of substantially parallel elements 1a, 1b which are positioned to receive a simple snap fixture 40 which is affixed to the surface of the heart. In this embodiment, the snap fixture 40 is positioned between the two parallel elements 1a, 1b of the contact ~~member~~ members 1, in order to fix the position of the heart tissue relative to the contact members 1. As in the above embodiments embodiment, the contact members 1 are preferably oriented in a substantially parallel fashion with the target artery of the anastomosis passing therebetween. The snap fixtures 40 are affixed to the heart by a suture, wherein the suture line 41 may then also be attached to the contact member 1 via a notch, which may form a one-way locking mechanism to secure the suture line 41, or may be attached to a circular post disposed in the body of the contact member 1. The suture line 41 then may be tied through the notch or to the post in the contact member 1 to more tightly secure the heart to the contact member 1. An additional advantage of this

embodiment is that the stabilizing means is actually affixed to the cardiac tissue via the suture line 41, such that when the heart is moving laterally or downward the artery being stabilized remains immobile.

Please amend the paragraph beginning on line 1 of page 25 as follows:

(Amended) occluder is a rigid member having a smooth outer surface for contacting and depressing the target artery without damaging the tissue. The planar surface 62 of the stabilizing means also has an aperture 64 comprising an opening which ~~traverses the entire joins the periphery of the~~ planar surface 62 with the centrally disposed opening 61 so that the anastomosis can be passed through the aperture 64 when the anastomosis is completed. The planar surface 62 may also provide a mounting surface for sprung tissue retractors 65 comprising a coiled spring 66 attached to the planar surface at one end and having a hook or pin 67 at the opposite end to engage and spread the tissue proximate to the anastomosis site to improve the exposure of the target artery. The planar surface 62 is attached to a post 69 which may be attached to a stable support such as the rib retractor as shown in Figure 9B 9b. The planar surface 62 may also have at least one port 70 for receiving a suture line.

Please amend the paragraph beginning on line 11 of page 25 as follows:

(Amended) Referring to Figure 8, the stabilizing means may have operably associated therewith an artery occluder 42, which is preferably attached to the contact members 1 or to the connecting shaft 2. The artery occluder 42 may comprise a semi-rigid member which has a blunt portion 43, which may be positioned such that the blunt portion 43 engages the target artery 55 and compresses the target artery 55 to a point causing occlusion of the target artery 55 passing between the contact members 1 such that the blood flow through the artery is substantially reduced or eliminated. Preferably, the occluder 42 has a shaft portion 44 which traverses the connection shaft 2 such that the blunt portion 43 of the occluder 42 43 may move from above the level of the target artery 55 to a point sufficient to occlude the blood flow.

Please amend the paragraph beginning on line 9 of page 26 as follows:

(Amended) Referring to Figure 9B, the stabilizing means 54 is an embodiment substantially as described above and shown in Figure 1 which ~~is comprised of~~ comprises a pair of rectangular, substantially planar contact members 1 which are placed proximate to a target artery 55. The shaft

means 3 is conformable such that it may be conveniently attached to the rib retractor 50. As shown in Figure 9B, the surgeon may readily adjust the orientation and positioning of the contact members 1 relative to the shaft means 3 while the stabilizing means 54 is in continuous contact with the heart by manipulating the thumbscrew 8 at the proximal end of the instrument.

Please amend the paragraph beginning on line 1 of page 27 as follows:

(Amended) of the invention may therefore be advantageously attached to a fixture attached to a rib retractor 50 or may be configured to be directly incorporated into the body of a portion of the rib retractor 50.

Please amend the paragraph beginning on line 1 of page 28 as follows:

(Amended) Referring to Figure 11, rib retractor 50 is shown in an open position whereby blades 53 engage and spread the ribs. A pair of stabilizing bars 72 having a conventional ratchet means 73 attached at the end thereof are positioned beneath the retractor. The ratchet means 73 comprises is comprised of a plurality of teeth 74 on the stabilizing bars 72 and a ratcheting aperture 75 permitting one-way passage of the stabilizing bars 72 unless released by a release mechanism. The stabilizing bars 72 are curved downward such that as the bars are advanced through the ratchet means 73, the lowermost portions portion 76 of the stabilizing bars 72 engage engages the beating heart proximate to the anastomosis site.